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1 RECORD OF ORAL HEARING
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3 UNITED STATES PATENT AND TRADEMARK OFFICE
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5
6 BEFORE THE BOARD OF PATENT APPEALS
7 AND INTERFERENCES
8

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10 *Ex Parte* STEVEN A. GOLDMAN and SU WANG
11

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13 Appeal 2011-012422
14 Application 09/282,239
15 Technology Center 1600
16

17
18 Oral Hearing Held: January 19, 2012
19

20
21 Before TONI R. SCHEINER, ERIC B. GRIMES, and
22 STEPHEN WALSH, *Administrative Patent Judges*.
23

24 APPEARANCES:

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34 The above-entitled matter came on for hearing on Thursday,
35 January 19, 2012, at the U.S. Patent and Trademark Office, 600 Dulany
36 Street, Alexandria, Virginia, before David Voigtsberger, a Notary Public.
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1 PROCEEDINGS

2 THE USHER: Calendar No. 79, Appeal No. 2011-012422,
3 Mr. Goldman.

4 JUDGE SCHEINER: Thank you. Good afternoon. Mr. Goldman,
5 are you the Inventor?

6 MR. GOLDMAN: I am not.

7 JUDGE SCHEINER: Oh, okay.

8 MR. GOLDMAN: I am Michael Goldman, and the Inventor is Steven
9 Goldman.

10 JUDGESCHEINER: I see. Oh, yes. Now I see that. Okay. Before
11 you get started, I wanted to let you know that Judge Walsh is joining us from
12 a remote site, and --

13 MR. GOLDMAN: Good afternoon.

14 JUDGE WALSH: Good afternoon.

15 COURT REPORTER: And if you have a business card, I'd
16 appreciate it.

17 MR. GOLDMAN: Sure. Thank you.

18 JUDGE SCHEINER: And before you do get started, I would like to
19 suggest that you spend the bulk of your time on the art rejection.

20 MR. GOLDMAN: Certainly.

21 JUDGE SCHEINER: Okay.

22 MR. GOLDMAN: Okay. Well, good afternoon. I'm here to discuss
23 the appeal from the Examiner's final rejection. Subject matter is an enriched
24 or purified preparation of human mitotic oligodendrocyte progenitor cells.

1 This is a collection of cells that are in the differentiation scheme between
2 stem cells and between fully differentiated oligodendrocytes.

3 The important thing about the claims is -- every limitation is
4 important, but the key ones, I would say, are the fact that these are human
5 cells and that they differentiate preferentially to oligodendrocytes.

6 JUDGE SCHEINER: Okay. Can we -- can I interrupt you right
7 there?

8 MR. GOLDMAN: Certainly.

9 JUDGE SCHEINER: I just want to make sure that we're all
10 understanding the claims the same way. This is a population of cells that
11 will -- the majority of which will mature into oligodendrocytes, if and when
12 they're cultured in the manner discussed in the body of the claim.

13 MR. GOLDMAN: That's correct.

14 JUDGE SCHEINER: Okay. But it's the actual, the population that's
15 being claimed, not the treated -- or, well, for lack of a better word, the
16 subsequently cultured population.

17 MR. GOLDMAN: It's the oligodendrocyte progenitor cell
18 population, not the oligodendrocytes that we're claiming.

19 JUDGE SCHEINER: No, no, no. I understand that, but I just want to
20 understand that presumably, if this population of cells is cultured in
21 something else, you don't necessarily get the majority maturing into
22 oligodendrocytes. Is that a fair --

23 MR. GOLDMAN: I'm not sure about that.

24 JUDGE SCHEINER: Okay.

1 MR. GOLDMAN: It could be that they differentiate in some other
2 way, and get some other result, is the idea.

3 JUDGE SCHEINER: Okay.

4 MR. GOLDMAN: So we wanted to be clear that it was using that
5 culture condition.

6 JUDGE SCHEINER: Okay. Because when we start talking about
7 example 7 in the reference, I'm going to have a couple questions about that.

8 MR. GOLDMAN: I imagine you would.

9 JUDGE GRIMES: While we're still looking at the claim, is there a
10 difference between 04-positive oligodendrocytes and galactocerebroside-
11 positive oligodendrocytes and oligodendrocytes?

12 MR. GOLDMAN: I think it depends on what the -- I mean, the
13 answer is yes. I think it depends on the source, and this is probably pretty
14 key to the idea of rats versus humans. So for example, you know, this has
15 been our argument, is rats are different than -- here you go. Besides their
16 being different, the cells are different as well. So in rats, the
17 oligodendrocytes are mitotic. They produce, they divide, and the oligos and
18 the -- the oligodendrocytes themselves and the progenitors will express as a
19 04 marker. But on the other hand, when you look at humans, only the
20 oligodendrocyte progenitors -- or, the oligodendrocyte -- yeah, only the
21 oligodendrocytes express that, but not the progenitors.

22 JUDGE SCHEINER: Can I interrupt you again?

23 MR. GOLDMAN: Sure.

24 JUDGE SCHEINER: *Rao* -- am I pronouncing that correctly? *Rao*?

25 MR. GOLDMAN: *Rao*. Yes.

1 JUDGE SCHEINER: In figure 1, their cell that they've labeled 14,
2 which is progenitor of oligodendrocytes and astrocytes is labeled 04-
3 negative. Now, I understand this is just a diagram, but --

4 MR. GOLDMAN: And it's also modeled on rats.

5 JUDGE SCHEINER: Right. I understand that. But I -- didn't I just
6 understand you to say that rat progenitors are 04-positive?

7 MR. GOLDMAN: Let me see. Yeah, the problem is 14 is not rat
8 progenitor. It's a less-differentiated state of cells. So as you can see from
9 the diagram in figure 1, those cells can either differentiate to astrocytes or
10 oligodendrocytes. And in fact, this is --

11 JUDGE SCHEINER: Okay. I know we're jumping around a lot --

12 MR. GOLDMAN: That's okay.

13 JUDGE SCHEINER: But, you know, your claim seemed to be based
14 on the results that you got in example 6 in the specification? Is that correct?

15 MR. GOLDMAN: Certainly --

16 JUDGE SCHEINER: I mean, that's one basis we know.

17 MR. GOLDMAN: Yeah. Certainly.

18 JUDGE SCHEINER: Okay. And example 6, there were some
19 astrocytes, and even some neurons observed.

20 MR. GOLDMAN: That's right. But we're not saying there are no
21 astrocytes. That's the majority limitation.

22 JUDGE SCHEINER: Okay. Right.

23 MR. GOLDMAN: So the difference between our claims and what
24 *Rao* is doing is that the majority are actually astrocytes.

1 JUDGE SCHEINER: Okay. That's one thing. Can you show us
2 where there's evidence of that in -- that *Rao* got a majority of astrocytes?

3 MR. GOLDMAN: Sure. Examples 14 and 15 of *Rao* in the
4 reference.

5 JUDGE SCHEINER: Okay. Let me get there. Sorry, I know we're
6 clicking all over the place up here. We have all this on the screens up here.

7 MR. GOLDMAN: I do it the old-fashioned way.

8 JUDGE SCHEINER: You said 14 and 15?

9 MR. GOLDMAN: Yeah.

10 JUDGE SCHEINER: Okay. Well, let me make sure I understand the
11 earlier examples first. And I know I'm interrupting your flow here, but I do
12 have questions.

13 MR. GOLDMAN: I'm here to explain the case to you, for your
14 questions.

15 JUDGE SCHEINER: Okay, the first several examples in *Rao*, it
16 looks like they're all the same cells, and what they did was they cultured
17 them after the initial isolation from -- was it neural tube?

18 MR. GOLDMAN: Of fetal rats. That's right.

19 JUDGE SCHEINER: Fetal rats, yes. I do know that they were rats.
20 The next several examples are taking those same cells and culturing them
21 under different conditions and under 1, if I understand the examples
22 correctly, under example 2, they culture them with certain factors and they
23 get -- well, let's see -- in one case, they get neurons. In one case, they get
24 predominantly astrocytes, and in one case, they get -- yes, in example 5, they
25 get neurons. Example 6, they get -- seems to be astrocytes?

1 MR. GOLDMAN: Yeah. I mean, I don't know if they really -- they
2 talk about all of this, but I don't think they get into, you know, quantifying
3 the yield of one or the other.

4 JUDGE SCHEINER: Exactly. And that's why -- that's where my
5 question comes in, because in example 7, they get -- they, under certain
6 culture conditions, they seem to get predominantly -- I mean, or at least --
7 it's true that they don't -- there are no percentages here, but they're focusing
8 on the oligodendrocytes.

9 MR. GOLDMAN: But see, the thing is --

10 JUDGE SCHEINER: So how are examples 14 and 15 different?

11 MR. GOLDMAN: Well, the first thing I'd like to point out is that
12 Dr. Rao has put in two declarations in support of our patentability

13 JUDGE SCHEINER: No, I understand that.

14 MR. GOLDMAN: And Dr. Rao, in that, has pointed out that he
15 regards his method as astrocyte-biased, as far as he's -- progenitor cells, 14.

16 JUDGE SCHEINER: Right. But I was -- we were looking for
17 evidence in those declarations.

18 MR. GOLDMAN: Right. Well, I think I would read 7 as just silent on
19 the issue.

20 JUDGE SCHEINER: Okay.

21 MR. GOLDMAN: I don't think 7 speaks to it one way or the other,
22 whereas 14 and 15 very clearly do.

23 JUDGE SCHEINER: Okay. So let's -- if you could walk us through
24 14 and 15, then.

1 MR. GOLDMAN: Sure. So, well, I'll just go -- on 14, if you go just
2 to the conclusion, I mean, it says that the -- it's the last, in column 20,
3 paragraph -- well, yeah, the paragraph that begins on line 53 and it concludes
4 with the culture consists of 30 percent astrocyte and 50 percent -- or, I'm
5 sorry, 30 percent oligodendrocytes, 50 percent astrocytes, and 20 percent
6 other, so -- and they're talking about these A2B5 -- I believe what they're
7 referring to -- it's not, you know, as clear as it could be, but I believe what
8 they're talking about is that in the context of the drawing of figure 1, nothing
9 else makes sense -- that what happens to 14 when they culture under these
10 conditions is they get a preference for astrocytes, which is not what we want
11 and not what we claim.

12 JUDGE SCHEINER: And then the next?

13 MR. GOLDMAN: And example 15 is, this is actually if you look in
14 column 22, lines 9 through the end of that paragraph, it says the result
15 suggested that in the presence of these agents, the A2B5 cells predominantly
16 differentiated the cells with a type-2 astrocyte, astrocyte phenotype.

17 JUDGE SCHEINER: The CNTF bFGF, are those -- then you've got
18 FGF-2 in the claim. They're not -- you know, they're not --

19 MR. GOLDMAN: I mean, you know, they are identical cultural
20 conditions, but on the other hand, there's nothing to indicate that something
21 will change here from what they're teaching based on the culture conditions.
22 And again, Dr. Rao has testified that these cells are astrocytic bias, they have
23 an astrocytic bias. And that's not what we want.

24 JUDGE SCHEINER: These are the same -- so 14 and 15 start out
25 with the same cells that examples 5, 6, and 7 do?

1 MR. GOLDMAN: That's my read on it.

2 JUDGE SCHEINER: Okay. But don't examples 5, 6, and 7 show
3 that the culture conditions are critical? That you do get different --

4 MR. GOLDMAN: Well, I guess what I view them as is they're just
5 studying the different aspects of what's shown in figure one, as far as these
6 different parts of the differentiation scheme. So I don't know that they're
7 doing anything other than going through and showing what happened at each
8 one of these different stages, and then finally, when they get around to 14
9 and 15, they studied, you know, the actual bias of these bipotential cells.

10 JUDGE SCHEINER: Okay. Can we go back for a minute now and
11 just look at now -- okay, our claim is human cells.

12 MR. GOLDMAN: Right.

13 JUDGE SCHEINER: *Rao* is rat cells.

14 MR. GOLDMAN: True.

15 JUDGE SCHEINER: And there is a mention in there that this
16 procedure of theirs, where they're taking -- they're teasing cells out of neural
17 crest and then doing, you know, clonal so on and so forth.

18 MR. GOLDMAN: Right.

19 JUDGE SCHEINER: They're not doing a FACS, a fluorescence-
20 activated cell sorting procedure. But there is a suggestion in here that you
21 could take *Rao*'s -- that *Rao* suggests that you could take this procedure and
22 apply it to human cells.

23 MR. GOLDMAN: Okay. I guess I would differ with that. I think,
24 you know, the Examiner has certainly seized on, and I guess it's column 6 --

1 JUDGE SCHEINER: So I guess what we'd like to focus on is -- I
2 mean, I understand that your -- correct me if I'm wrong, but I think your
3 position, in part, is that you don't have an actual anticipation because of --
4 because this is rat, not human, and that the reference is not enabling for
5 human.

6 MR. GOLDMAN: That's right.

7 JUDGE SCHEINER: Can you focus on the evidence that establishes
8 that -- that you feel establishes that this is not an enabling reference?

9 MR. GOLDMAN: Not enabling for human?

10 JUDGE SCHEINER: For human, yes.

11 MR. GOLDMAN: Yeah. I mean, I don't have any issue with the ref.

12 JUDGE SCHEINER: Right.

13 MR. GOLDMAN: I mean, the only -- basically, all the work is done
14 with rats. There's a slight mention of use in human, but really, when you
15 read it, it's just about these stem cells that are upstream of the cells that have
16 the bipotential differentiation. So it's not really clear what they're trying to
17 say, but I think the evidence that we've put into the record is that rats and
18 humans are pretty different. And I believe the declarations of Dr. Goldman
19 speak to that.

20 JUDGE SCHEINER: Okay. We have at least two, is that correct?

21 MR. GOLDMAN: There's two. It's the first, and the third. And I
22 believe they're both in paragraph 7.

23 JUDGE SCHEINER: Okay.

24 MR. GOLDMAN: Of each. So the -- in those declarations -- and I
25 could pull them out and read them if you want -- but basically, they talk

1 about how the rat oligos themselves, oligodendrocytes, are mitotic and the
2 human oligodendrocytes aren't and that the rat oligodendrocytes and their
3 progenitors express the same markers, while the human ones don't.

4 JUDGE SCHEINER: But that's actually not consistent with *Rao*, is
5 it? Well, at least the earlier cell that they had.

6 MR. GOLDMAN: Well, see, but I don't think what we're talking
7 about there is what *Rao* really deals with. And what *Rao* -- that, yeah, I
8 don't think --

9 JUDGE SCHEINER: Oh, no, I understand that's your position. I'm
10 just looking for the evidence --

11 MR. GOLDMAN: 14 is not an oligodendrocyte progenitor, except in
12 the broadest -- in the way we're claiming it. It's a progenitor that will
13 actually differentiate either to astrocytes or oligos, but it -- with the bias
14 being to the astrocytes. And so what we're talking about is something that --
15 and it's claimed, I think, that our progenitors --

16 JUDGE SCHEINER: Oh, no, I do understand that. I'm just looking
17 for some hard evidence.

18 MR. GOLDMAN: Okay. Okay, well I think the declaration does
19 point out that there are profound differences between humans and rats, and
20 the idea that one would be able to go from results with humans, given the --
21 from rats, given the differences that are presented in the declaration to rats is
22 pretty tough to fathom.

23 I mean, the evidence also is that this was quite a big event when our
24 Inventors did this. It's published in *Nature Medicine* as being the first time
25 that the human oligodendrocyte progenitor cells were isolated, and there was

1 much talk about why that was scientifically interesting for that reason, but
2 also therapeutically interesting in that it would provide a vehicle to treat
3 such diseases as multiple sclerosis and other diseases involving
4 demyelination or the inability to produce it.

5 So I think the evidence -- there's really not much evidence to support
6 the Examiner's position, frankly, on this, other than he tries to kind of tie
7 well, this little mention of human over here, and then it's generic in the
8 drawings, and then it got this rat cell stuff that should just be put together.

9 And I just don't think there's any evidence to support the position that
10 humans -- or rat work is germane to what you'd expect with human work.

11 And I have a problem -- you know, the biggest problem I think we've had is
12 what kind of reference is this reference? Is it an anticipatory reference, or is
13 it one of obviousness? I think --

14 JUDGE SCHEINER: Is it -- oh, it's actually applied 102, 103. Is that
15 correct?

16 MR. GOLDMAN: Well, he ties -- yeah. And the problem is that
17 okay, maybe when you look at the general, you know, at the mention of
18 humans, you could say okay, well, that's about humans. But everything else
19 is either generic or it's about rats. And I think once you move to the
20 examples, we're talking -- I don't see how that reference continues to be an
21 anticipatory reference, because the data is all about rats, and the evidence is
22 that rats are, you know, again -- it sounds silly -- are different than humans.

23 JUDGE SCHEINER: Right.

24 MR. GOLDMAN: Sorry. So, I, you know, I think we put a lot of
25 evidence into the record based on what we were faced with at the -- during

1 prosecution to demonstrate that this was not an appropriate rejection. And
2 again, Dr. Rao also supports the idea that this is a very different
3 phenomenon in that we're getting the bias to the oligodendrocytes, which is
4 what you need to be able to treat these diseases of demyelination. Having an
5 astrocytic bias doesn't help you, in that regard.

6 JUDGE SCHEINER: I'm sorry that I sort of jumped in, and I'm sure
7 you had some kind of a presentation. Would you like to give it now, or do
8 you --

9 MR. GOLDMAN: I'll just say a few more things.

10 JUDGE SCHEINER: Okay.

11 MR. GOLDMAN: But basically, you've, you know, it was fine.

12 JUDGE SCHEINER: Okay.

13 MR. GOLDMAN: One word about -- one word, or a few words about
14 the 112 rejection.

15 JUDGE SCHEINER: Yes. Okay.

16 MR. GOLDMAN: Basically, I think we've said our piece on it for the
17 most part, but it seems like the issue is that we have the word
18 oligodendrocyte in there. Well, the record is pretty clear on -- and I can
19 point you to evidence of that -- that these 04 cells in the context that they
20 were doing that experimental work, were oligodendrocytes. And again, the
21 *Goldman* declaration, paragraph seven, the *Goldman*, the third one, said,
22 points out that these --

23 JUDGE SCHEINER: Third? Oh, I'm sorry. I seem to only have two
24 *Goldman* declarations.

25 MR. GOLDMAN: Oh, there was three.

1 JUDGE SCHEINER: I will go into the record and --

2 MR. GOLDMAN: One's called the third. One's called the third.

3 JUDGE SCHEINER: Oh, it's called the third. Okay. Oh, yeah. I'm
4 sorry. We do have --

5 MR. GOLDMAN: Because I don't know if the second one actually
6 is --

7 JUDGE SCHEINER: We do have that. Sorry.

8 MR. GOLDMAN: Yeah. So I think it was, like, in paragraph seven
9 when we talk about how the oligodendrocytes are recognized by antibodies
10 that have this, you know, are looking for this 04 marker. So I think the idea
11 that --

12 JUDGE SCHEINER: Well, I think the Examiner in the response
13 mentioned that Schwann cells also have 04 --

14 MR. GOLDMAN: But in the context of what we're disclosing, it's
15 not just the general -- so I think in the context of the basis for that argument,
16 I think we're in pretty good shape as far as not being new matter. The other
17 thing I wanted to point -- a couple things I wanted to point out. If, first of
18 all, if you agree with us on those claims with the percentages of the -- well,
19 claims 42 to 44 --

20 JUDGE SCHEINER: You know we don't tell you anything around
21 here.

22 MR. GOLDMAN: I know. But if you, you know, agree that there's
23 not a 112 problem, I don't see how *Rao* gets close to that. They're talking
24 about an astrocytic bias, and we're talking about a higher percentage of
25 claims being -- a specific percentage being oligodendrocytes. And the only

1 other thing I wanted to mention was that we think the human fetal distinction
2 is also worth paying attention to.

3 JUDGE SCHEINER: Fetal versus adult, you mean?

4 MR. GOLDMAN: Yes. Sorry. Thank you. So basically, we have
5 certain claims that are limited to adult, and we think we presented evidence
6 that adults are different -- again, silly sounding -- but adults are different
7 than fetal, so the extent you're looking at *Rao*, it's fetal, and we don't see
8 how that is a basis to reject the adult, even if you think the examples would
9 otherwise be suitable to reject our more generic claims.

10 And I think we decided to -- Dr. Rao's first declaration, paragraph
11 eight, where we pointed out that there are, you know, significant differences
12 between the two. And again, if that's something that you agree with us on,
13 claims 26 and 42, 43, would be patentable regardless of how you rule on the
14 others. So I don't have --

15 JUDGE SCHEINER: Okay.

16 MR. GOLDMAN: I got my piece in from your -- from answering
17 your questions, so --

18 JUDGE SCHEINER: All right. Well, I don't pretend to understand
19 this case completely yet, but I will before we --

20 MR. GOLDMAN: Okay. Well, thank you for your time.

21 JUDGE SCHEINER: Just, I'm sorry. Judge Walsh, did you have any
22 questions?

23 JUDGE WALSH: No. Thank you.

24 MR. GOLDMAN: Okay. Thank you.

25 JUDGE SCHEINER: Did you have anything?

- 1 JUDGE GRIMES: No.
- 2 MR. GOLDMAN: Okay. Thank you very much.
- 3 (Whereupon, the proceedings, at 2:30 p.m., were concluded.)